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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

ATTORNEY DOCKET NO. 052209-0143

Applicant: Marco FILICORI
Title: UNITARY COMBINATIONS OF FSH AND hCG
Appl. No.: 10/559,610
Filing Date: 01/31/2007
Examiner: Unassigned
Art Unit: 1614
Confirmation Number: 1532

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicant in order to comply with Applicant's duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicant does not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

RELEVANCE OF EACH DOCUMENT

The submitted documents are cited in the specification.

An English translation of foreign-language document B28 is not readily available. However, the absence of such translation does not relieve the PTO from its duty to consider the submitted documents (37 CFR §1.98 and MPEP §609). Moreover, this document is cited only for teaching methods of purifying hCG. See, e.g., page 11 of the specification.


Applicant respectfully requests that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

Although Applicant believes that no fee is required for this Request, the Commissioner is hereby authorized to charge any additional fees which may be required for this Request to Deposit Account No. 19-0741.

Respectfully submitted,

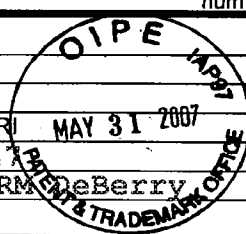
May 31, 2007
Date

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Attorney for Applicant
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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known	
Sheet	1	of	3	Application Number Filing Date First Named Inventor Art Unit Examiner Name Attorney Docket Number	10/559,610 06/02/2004 Marco FILICORI 1644 16413 Unassigned RMD DeBerry 052209-0143



U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
RMD	B1	5,656,597	08-12-1997	SKRABANJA et al.	
RMD	B2	5,929,028	07-27-1999	SKRABANJA et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
RMD	B3	ASCOLI, "Characterization of Several Clonal Lines of Cultured Leydig Tumor Cells: Gonadotropin Receptors and Steroidogenic Responses," Endocrinology, 1981, pages 88-95, Vol. 108, No. 1, The Endocrine Society.	
	B4	CAMPBELL et al., "Examination of the Relative Role of FSH and LH in the Mechanism of Ovulatory Follicle Selection in Sheep," Journal of Reproductive and Fertility, 1999, pages 355-367, Vol. 117, Journals of Reproduction and Fertility Ltd.	
	B5	CHANG et al., "Recombinant Human Chorionic Gonadotropin (rhCG) in Assisted Reproductive Technology: Results of a Clinical Trial Comparing Two Doses of rhCG (Ovidrel [®]) to Urinary hCG (Profasi [®]) for Induction of Final Follicular Maturation in <i>in vitro</i> Fertilization-Embryo Transfer," Fertility and Sterility, July 2001, pages 67-74, Vol. 76, No. 1, American Society for Reproductive Medicine.	
	B6	CHAPPEL et al., "Biosynthesis and Secretion of Follicle-Stimulating Hormone," Endocrine Reviews, 1983, pages 179-211, Vol. 4, No. 2, The Endocrine Society.	
	B7	CLASESSON L., et al., "Crystalline Human Chorionic Gonadotrophin and its Biological Action," ACTA Endocrinologica, 1948, Vol. I, pages. 1-18.	
RMD	B8	DIGHE et al., "Use of α - and β -Subunit Specific Antibodies in Studying Interaction of hCG with Leydig Cell Receptors", Archives of Biochemistry and Biophysics, September 1983, pages 490-499, Vol. 225, No. 2, Academic Press, Inc.	

Examiner Signature	ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH.	Date (03/10/2008)	Considered
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. 1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. 6 Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Application Number	10/559,610
		Filing Date	06/02/2004
(use as many sheets as necessary)		First Named Inventor	Marco FILICORI
		Art Unit	1644 1647
Sheet 2 of 3		Examiner Name	Unassigned RM DEB
		Attorney Docket Number	052209-0143

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
RMD	B9	FEVOLD, H. L. et al., "Studies in the Physical Chemistry of the Anterior Pituitary Hormones," Endocrinology, May 1940, Vol. 26, pages 999-1004.	
	B10	FILICORI et al., "Modulation of Folliculogenesis and Steroidogenesis in Women by Graded Menotrophin Administration," Human Reproduction, 2002, pages 2009-15, Vol. 17, No. 8, European Society of Human J Reproduction and Embryology.	
	B11	FILICORI et al., "The Use of LH Activity to Drive Folliculogenesis: Exploring Uncharted Territories In Ovulation Induction," Human Reproduction Update, 2002, pages 543-557, Vol. 8, No. 6, European Society of Human Reproduction and Embryology.	
	B12	FILICORI, "Use of Luteinizing Hormone In the Treatment of Infertility: Time for Reassessment?," Fertility and Sterility, February 2003, pages 253-255, Vol. 79, No. 2, American Society for Reproductive Medicine.	
	B13	FRAENKEL-CONRAT et al., "Purification of Follicle-Stimulating Hormone (FSH) of the Anterior Pituitary," Proc. Soc. Exp. Biol. Med., 1940, Vol. 45, pages 627-630.	
	B14	GORDON et al., Abstracts of the 13 th Annual Meeting of the ESHRE, 1997, pages 52-54, Edinburgh.	
	B15	GREEP, B. F., et al., "Separation in Nearly Pure Form of Luteinizing (interstitial Cell-Stimulating) and Follicle-Stimulating (Gametogenic) Hormones of the Pituitary Gland," J. Biol. Chem., 1940, Vol. 133, pages. 289-291.	
	B16	GUPTA et al., "Hyperexpression of Biologically Active Human Chorionic Gonadotropin Using The Methylootropic Yeast," Pichia Pinions, Journal of Molecular Endocrinology, 1999, pages 273-283, Vol. 22, Society of Endocrinology.	
	B17	HILLIER et al., 'Follicular Oestrogen Synthesis: The Two-Cell, Two-Gonadotrophin' Model Revisited,' Molecular and Cellular Endocrinology, 1994, pages 51-54, Vol. 100, Elsevier Science Ireland Ltd.	
RMD	B18	KATZMAN, P.A., et al., "The Preparation of Chorionic Gonadotropin by Chromatographic Adsorption," J. Biol. Chem., 1943, Vol. 148, pages 501-507.	

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Sheet	3	of	3		

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RMD	B19	KEENE et al., "Expression of Biologically Active Human Follitropin in Chinese Hamster Ovary Cells," The Journal of Biological Chemistry, March 25, 1989, pages 4769-4775, Vol. 264, No. 9, The American Society for Biochemistry and Molecular Biology, Inc.		
	B20	LI, et al., "Isolation of Pituitary Follicle Stimulating Hormone (FSH)," Science, 1949, Vol. 109, pp. 445-446.		
	B21	MARTIN et al., "ART: Ovarian Stimulation," Fertility & Sterility, October 14, 2002, page S19.		
	B22	MC SHAN, W.H., et al., "The Preparation and Properties of Pituitary Follicle-Stimulating Fractions Made By Trypsin Disgestion," J. Biol. Chem., 1940, Vol. 135, pages 473-482.		
	B23	REMINGTON'S PHARMACEUTICAL SCIENCES, 15 th Ed. (Mark Publishing Co. 1975), pages 1405-1412 and 1461-1487.		
	B24	SHOHAM, "The Clinical Therapeutic Window For Luteinizing Hormone in Controlled Ovarian Stimulation," Fertility and Sterility, June 2002, pages 1170-1177, Vol. 77, No. 6, American Society for Reproductive Medicine.		
	B25	SNYDER et al., "Characterization of Human LH Isohormones From Fresh Pituitary Tissue," Molecular and Cellular Endocrinology, 1987, pages 115-121, Vol. 54, Elsevier Scientific Publishers Ireland Ltd.		
	B26	VAN HELL, H., et al., "Effects of Human Menopausal Gonadotrophin Preparations in Different Bioassay Methods," ACTA Endocrinologica, 1964, Vol. 47, No. 3, pages 407-418.		
	B27	WARNE et al., "Induction of Ovulation in World Health Organization Group II Anovulatory Women Undergoing Follicular Stimulation with Recombinant Human Follicle-Stimulating Hormone: A Comparison of Recombinant Human Chorionic Gonadotropin (rhCG) and Urinary hCG," Fertility and Sterility, June 2001, pages 1111-1118, Vol. 75, No. 6, American Society for Reproductive Medicine.		
RMD	B28	Zondek and Aschheim, Klin, Wochenschr, 1928, Vol. 7, pages 931-932.		

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